

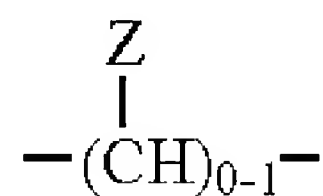
REMARKS

Claims 9-16 remain pending in this application. Claims 1-8 were previously canceled. Claims 9-13 have been withdrawn. Claims 14-16 were examined on the merits.

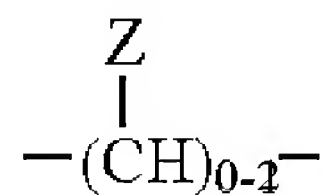
The specification, and claims 9, 10 and 13-15 have been amended. Support for the amendments can be found in the specification and original claims as filed. Support for the amendment to formula (I) can be found for example, at page 6, lines 15-18, and in the multiple exemplary dihydrobenzofuran compounds described throughout the specification, for example at pages 9-10. No new matter has been added.

AMENDMENT TO THE SPECIFICATION

Applicants amend the specification to more clearly define the α -aminoamide of formula (I). In particular, a portion of formula (I),



has been amended to



Support for this amendment to formula (I) can be found in the specification, at least at page 5, line 18, and at page 6,

lines 15-18, wherein X = O, and Y and Z taken together form a dihydrobenzofuran ring. Additional support for the amendment of formula (I) can be found by the numerous dihydrobenzofuran compounds that are represented by formula (I), and recited in the specification at pages 9-10. Thus, no new matter has been added by this amendment to formula (I).

CLAIM REJECTION - 35 USC § 112, SECOND PARAGRAPH

At page 2, the Office Action rejects claims 14-16 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Office Action points specifically to the term "isomers" and states that isomers could be formula isomers, stereoisomers, etc.; thus, the Office Action concludes that the scope of the claims is unclear. The Office Action states that replacing "isomers" with "stereoisomers" would overcome the rejection.

Amended claims 14 and 15 currently recite the "stereoisomers" term suggested in the Office Action. Thus, each of claims 14-16 distinctly defines the intended subject matter and each claim satisfies the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

CLAIM OBJECTION

At page 3, the Office Action objects to the claims for containing non-elected subject matter. The Office Action points out that the elected compounds are dihydrobenzofuran compounds of formula (I).

Amended claims 14 and 15, and claim 16, are directed to dihydrobenzofuran compounds of formula (I). The claims do not recite any non-elected subject matter. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

CLAIM REJECTION - 35 USC § 112, FIRST PARAGRAPH

At page 3, the Office Action rejects claims 14-16 under 35 U.S.C. § 112, first paragraph as not enabled. Applicants respectfully traverse the rejection.

The Office Action holds the position that the claims relate to compounds useful for treating lower urinary tract disorders because of their ability to block sodium channels. The Office Action further maintains that the specification includes biological data relating to potential utility but that data is drawn to compound NW-1029, which is not a dihydrobenzofuran, as specified in claim 14. The Office Action further maintains that there is a "substantial gap" between what is taught in the specification and what is being claimed.

The Office Action concludes that one of ordinary skill in the art would be faced with an undue amount of experimentation to identify a dihydrobenzofuran compound that would have any utility. Applicants respectfully disagree with this position.

First, claim 14 is directed to an α -aminoamide compound represented by formula (I) (currently restricted to a dihydrobenzofuran), and dependent claim 15 further specifies a group of particular α -aminoamide (dihydrobenzofuran) compounds. Claim 16 is directed to a pharmaceutical composition comprising the α -aminoamide compound of claim 14 as an active agent. As acknowledged in the Office Action, the specification fully enables one of ordinary skill in the art to produce the α -aminoamide compounds of claims 14-16. Indeed, the specification provides several examples detailing how to make the claimed compounds. Thus, the specification fully enables one of ordinary skill in the art to produce the α -aminoamide compounds of claims 14-16.

Contrary to the position taken in the Office Action, claims 14-16 do not recite that the compounds of formula (I) are used to treat lower urinary tract disorders, or that the compounds have the ability to block sodium channels. The claims are directed to α -aminoamide compounds of formula (I), and are fully enabled by the specification.

Second, one of ordinary skill in the art could, without undue experimentation, determine which compounds exhibit pharmacological activity. Evidence of predictability and enablement of the claimed compounds can be found in the attached Rule 132 Declaration of Patricia Salvati.

The Salvati Declaration demonstrates that α -aminoamide compounds can be screened for activity, and representative compounds, in particular dihydrobenzofuran compounds, can be found that inhibit sodium current transport and sodium channels. Compounds UPF794, UPF 824, UPF823, UPF802, UPF807 are representative dihydrobenzofuran compounds, prepared according to the Examples disclosed in the specification, that fall within the scope of formula (I), and within the scope of claims 14-16.

From the results presented in the Declaration, it is evident that the claimed compounds show a marked inhibition of TTC-R Na⁺ currents so that a corresponding efficacy in reducing bladder over-activity in animal models can be expected. Taken as a whole, the Rule 132 Declaration provides evidence to support the fact that claims 14-16 are fully enabled, and that each claim satisfies the requirements of 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

CLAIM REJOINDER

Applicants request rejoinder of the non-elected invention of claims 9-13, upon a determination of allowance of the elected invention, per U.S. rejoinder practice (See M.P.E.P. § 821.04). Claim 9 is directed to a method for treating urinary tract infection, comprising administering an effective amount of at least one therapeutic agent which is an alpha-aminoamide compound of formula (I).

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/H. James Voeller/
H. James Voeller, Reg. No. 48,015
Customer No. 00466
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

HJV/jr

APPENDIX:

The Appendix includes the following item(s):

- ☐ - a terminal disclaimer
- ☒ - a 37 CFR 1.132 Declaration
- ☐ - a new or amended Abstract of the Disclosure
- ☐ - a Replacement Sheet for Figure of the drawings
- ☐ - a Substitute Specification and a marked-up copy of the originally-filed specification
- ☐ - a verified English translation of foreign priority document